(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) Publication number: **0 646 390 A1**

(12) EUROPEAN PATENT APPLICATION

(21) Application number: **94111079.3**

(51) Int. Cl.[6]: **A61N 1/368**

(22) Date of filing: **15.07.94**

(30) Priority: **24.09.93 SE 9303121**

(43) Date of publication of application:
05.04.95 Bulletin 95/14

(84) Designated Contracting States:
DE FR GB IT NL

(71) Applicant: **Pacesetter AB**
Röntgenvägen 2
S-171 95 Solna (SE)

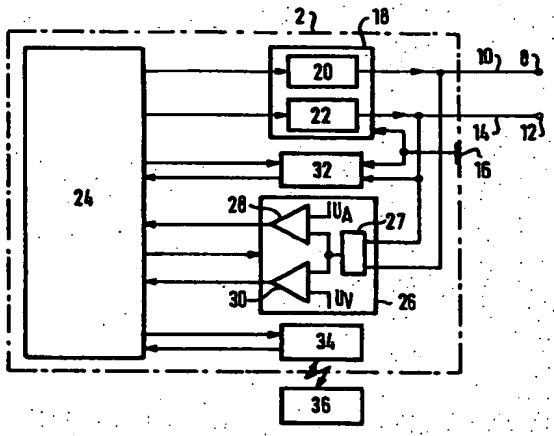
(72) Inventor: **Högnelid, Kurt**
Villavägen 306
S-137 38 Västerhaninge (SE)

(74) Representative: **Lettström, Richard Wilhelm et al**
H. ALBIHNS PATENTBYRA AB
Box 3137
S-103 62 Stockholm (SE)

(54) Heart stimulator.

(57) A heart stimulator (2), comprising an atrial electrode (8) in an atrium of a heart (4) and a ventricular electrode (12) in a ventricle in the heart (4), is described. In order to sense stimulated events in the heart, a detector (26) is connected to the electrodes (8, 12) in order to measure electrical heart signals between them.

FIG 2



EP 0 646 390 A1

The present invention relates to a heart stimulator comprising a pulse generator and an electrode system which comprises an atrial electrode, arranged in an atrium of a heart, and a ventricular electrode, arranged in a ventricle of the heart, whereby stimulation pulses, generated by the pulse generator, are delivered to the atrium via the atrial electrode or to the ventricle via the ventricular electrode for stimulating a heart response.

In a dual chamber system of the above-described type, the atrium and ventricle can be stimulated in a synchronous sequence which emulates a natural heart cycle in a healthy heart. In order to prevent the release of needless stimulation pulses to the heart, the atrium and the ventricle can be sensed for spontaneous activity. For example, if the ventricle is sensed for spontaneous activity, ventricular stimulation pulses are inhibited when a spontaneous ventricular event (ventricular systole) is sensed. Such a system is designated DVI. The DVI-system is further refined if the atrium is also sensed for spontaneous activity. A sensed spontaneous atrial event (atrial systole) would then inhibit emission of an atrial stimulation pulse. This refined system is known under the designation DDI. A heart stimulator is designated DDD if it is devised for both triggering and inhibiting according to spontaneous activity sensed in both the atrium and the ventricle.

EP-A-0 308 536 describes a heart stimulator which can stimulate and sense both in the atrium and ventricle. The known heart stimulator has two electrodes in the atrium (atrial electrodes), two electrodes in the ventricle (ventricular electrodes) and an indifferent electrode, consisting of the heart stimulator's capsule. Stimulation and sensing of both the atrium and the ventricle can be achieved either between an electrode and the capsule or between the two electrodes in the respective chamber, i.e. atrial stimulation and sensing between one atrial electrode and the capsule or between two atrial electrodes and ventricular stimulation and sensing between one ventricular electrode and the capsule or between two ventricular electrodes.

The electrodes are implanted in the heart on electrode leads. For the known heart stimulator, a bipolar electrode lead can be implanted in the atrium, and a bipolar electrode lead can be implanted in the ventricle. The electrode emitting the stimulation pulses must be in contact with heart tissue in order to stimulate same. However, a sensing electrode does not need to be in contact with heart tissue, since blood in the heart conducts current better than the tissue itself. But it is preferable to have even the sensing electrode in contact with heart tissue, since this will result in more distinct signals. This is because an electrode which is not in direct contact with tissue picks up signals from a large area of tissue. In addition, interference signals are conducted better in blood than in tissue and thus affect the measurement signal to a greater degree.

As an alternative to two bipolar electrode leads, a quadripolar electrode lead can be used, provided it is constructed so at least one of the two electrodes located in the atrium is in contact with heart tissue for stimulating same. The advantage of a quadripolar electrode lead is that it facilitates implantation, since only one electrode lead has to be introduced into the heart. The disadvantage of a quadripolar electrode lead is that it is thicker and stiffer than a bipolar electrode lead.

In EP-A-0 596 319, which was published after the filing of the prior Swedish application on which the present application is based, a heart stimulator which has an electrode system for sensing atrial and ventricular heart events is described. The electrode system has one atrial electrode, one ventricular electrode and an indifferent electrode, consisting of the heart stimulator's capsule. Ventricular events are sensed in the same way as in the above-described known heart stimulator, i.e. between the ventricular electrode and the indifferent electrode. Spontaneous atrial activity is sensed between the atrial electrode and the ventricular electrode. With this design, the number of conductors in the electrode lead can be reduced compared to when a separate sensing electrode is used, as in the above-described known heart stimulator.

In order to operate as effectively as possible in the DDD mode, the heart stimulator should automatically ascertain whether emitted stimulation pulses result in any heart events, i.e. evoked responses. If provided with such a function, the heart stimulator will have an ability to automatically set the stimulation amplitude at a value which is as close to the heart's stimulation threshold value as possible, thereby saving energy. This function is known as autocapture.

One problem here is to distinguish between signals with different origins in the heart without the need for excessively comprehensive electronics or circuit logic. Heart stimulators are designed so they do not impede nor disturb the patient receiving the heart stimulator. Therefore, the volume and weight of the heart stimulator are restricted as much as possible, and this naturally limits the possibility of incorporating comprehensive electronics in the stimulator.

One object of the invention is to achieve a heart stimulator which can simply and safely detect spontaneous and evoked heart responses and which solves the above-described problems.

One such heart stimulator is achieved in accordance with the invention in that a detector is connected to the atrial electrode and the ventricular

electrode for sensing stimulated ventricular heart events.

In conjunction with the emission of a ventricular stimulation pulse, a detector is activated to sense the signal between the ventricular electrode and the atrial electrode. If a ventricular heart event is stimulated by the ventricular stimulation pulse, the electrical signal in the heart tissue (the depolarization signal) will be sensed, and the detector will generate a signal which indicates that an evoked response has occurred in the heart. So only two electrodes are used for sensing evoked ventricular heart events. As a result of differences in polarity and signal strength between atrial and ventricular signals and, particularly, differences in logic structure and function, a detector devised according to the known heart stimulator in EP-A-0 596 319 is unable to detect any stimulated ventricular events, even though it can detect atrial events between an atrial electrode and a ventricular electrode. For example, the blanking functions, i.e. the time windows in which the detector does not sense any signals, are completely different.

It is advantageous if heart stimulators according to the present invention are devised so that a control device is connected to the detector for activating same for a predetermined time window in conjunction with the pulse generator's emission of ventricular stimulation pulses in order to sense stimulated ventricular heart events.

The detector can contain a special electronic circuit for conditioning the measurement signal after a ventricular stimulation pulse, said circuit being activated by a switch controlled by the logic circuit. In order to minimize space requirements, activation can be devised as a purely logical operation, i.e. a signal from the detector is accepted as an evoked response only if received in the predetermined time window. This is possible due to an understanding of the heart's physiology. A heart signal originates either in the atrium or the ventricle. After an atrial event (spontaneous or stimulated), the atrium needs time to recover before a new atrial event (spontaneous or stimulated) can occur. The recovery time required (refractory period) varies, but it cannot be shorter, in principle, than the repolarization time of atrial heart cells. In normal conditions, the heart beats at a rate of 70 to 150 beats a minute. Under normal conditions, atrial responses therefore occur at intervals which are never less than about 400 ms (150 bpm = 2,5 Hz which corresponds to 400 ms). Between these intervals the atrial electrode can be used as a reference for the ventricular electrode in the sensing of evoked ventricular signals. The time window is appropriately chosen so as to minimize the effect in case of abnormal atrial activity.

One advantageous refinement of the heart stimulator is obtained in accordance with the invention in that the detector is devised to also sense stimulated atrial heart events and in that the control device activates the detector in conjunction with every nth atrial stimulation pulse for sensing stimulated atrial heart events, n being a whole number, preferably between 1 and 6.

From the patient safety point of view, each ventricular stimulation pulse should be checked to determine whether it stimulates a response. For the atrium, however, it is sufficient to check the stimulation pulse at regular intervals to make sure that the atrial stimulation pulses are still effective. Even for the atrium, activation of the detector can be performed physically by a switch or by a logic function.

In conjunction herewith, it is advantageous if the pulse generator generates a biphasic atrial stimulation pulse or some other polarization-compensating stimulation pulse when a stimulated atrial event is to be sensed. The biphasic, or polarization-compensating stimulation pulse ensures that the atrial electrode does not acquire any residual polarization after the stimulation pulse is emitted. Detection of the stimulated event is thereby facilitated. The ventricular stimulation pulse can also be devised in a corresponding manner to facilitate detection of stimulated ventricular events.

A refinement of the heart stimulator is achieved in accordance with the invention in that the electrode system comprises an indifferent electrode, located outside the heart, in that a further detector is connected to the ventricular electrode and the indifferent electrode for sensing spontaneous ventricular events, and in that the further detector is activated at the same time as the detector is activated in order to sense stimulated atrial events.

If an abnormal ventricular event occurs, i.e. a ventricular extra systole (VES), it is advantageous if the heart stimulator is able to distinguish between stimulated atrial events and spontaneous VES's. This is achieved by adding a further detector which senses the ventricle at the same time as atrial measurement is performed. The indifferent electrode can appropriately consist of the heart stimulator's capsule (in part or whole). If both detectors sense an event, it cannot be determined that a stimulated event has occurred in the atrium. Sensing of the atrium should then be repeated.

In conjunction with sensing of atrial heart events after every nth atrial stimulation pulse, repetition of sensing is advantageously made after the next, consecutive atrial stimulation pulse when both detectors have sensed an event.

Referring to the figures, one embodiment of the heart stimulator according to the invention will now be described in more detail, whereby

FIG. 1 shows a schematic rendition of the heart stimulator connected to a heart;

FIG. 2 shows a block diagram of the heart stimulator;

FIG. 3 shows a first alternative version of a detector in the heart stimulator; and

FIG. 4 shows a second alternative version of the detector in the heart stimulator.

As shown in FIG. 1, the heart stimulator 2 is connected to a heart 4 by means of an electrode system 6. The electrode system 6 has an atrial electrode 8, which is arranged in the atrium of the heart 4. Via an atrial electrode conductor 10 can electrical signals be carried between the atrial electrode 8 and the heart stimulator 2. Further, a ventricular electrode 12 is arranged in the ventricle of the heart 4, and electrical signals can be carried between the ventricular electrode 12 and the heart stimulator 2 via a ventricular electrode conductor 14. The heart stimulator 2 also has an indifferent electrode 16 which can consist of a part or all of the heart stimulator's 2 capsule.

In FIG. 2 the structure of the heart stimulator 2 is schematically shown in a block diagram. Both the atrial electrode 8 and the ventricular electrode 12 are connected to a pulse generator 18, via the atrial electrode conductor 10 and the ventricular electrode conductor 14. The pulse generator 18 generates and emits atrial stimulation pulses from an atrial pulse generator 20 and ventricular stimulation pulses from a ventricular pulse generator 22. Both the atrial pulse generator 20 and the ventricular pulse generator 22 are controlled by a control device 24. The control device 24 controls the shape, amplitude, duration, stimulation interval etc. of the stimulation pulses.

The indifferent electrode 16 is also connected to the pulse generator 18, in order to form a common return line for atrial and ventricular stimulation pulses delivered to the heart 4 via the atrial electrode 8 and the ventricular electrode 12 respectively. A stimulation pulse returns through body tissue via the indifferent electrode 16 to the pulse generator 18.

The atrial electrodes 8 and the ventricular electrode 12 are connected to a detector 26 via the atrial electrode conductor 10 and ventricular electrode conductor 14. The detector 26 comprises a signal conditioning unit 27, an atrial comparator 28 and a ventricular comparator 30. Since ventricular depolarization signals are much stronger than atrial depolarization signals, two different reference signals are used for the comparators 28, 30. Signal conditioning in the signal conditioning unit 27 can be identical for the signals from both the atrium and ventricle and comprise e.g. signal filtering and amplification. The signal conditioning unit 27 can also be devised so detected signals are filtered in different ways, depending on whether they have a spontaneous or stimulated origin. Stimulated events can only follow an emitted stimulation pulse, so devising the signal conditioning detector 27 to achieve this differential filtering is therefore no problem.

The output signal from the signal conditioning unit 27 is subsequently compared in the atrial comparator 28 with an atrial reference potential U_A. If the output signal is larger than the reference potential, a detection signal is sent from the atrial comparator 28 to the control device 24.

However, the control device's 24 logic must be activated for receiving atrial events if the detection signal from the atrial comparator 28 is to be accepted as an atrial event.

In the corresponding manner, the output signal from the signal conditioning unit 27 is compared in the ventricular comparator 30 with a ventricular reference potential U_V. A detection signal from the ventricular comparator 30 is only accepted as a ventricular event if the control device's 24 logic has been activated for receiving ventricular events.

The control device 24 also controls the detector 26. It determines e.g. when the detectors 28, 30 are to be activated and the sensitivity with which heart signals are to be sensed.

A further detector 32 is connected to the ventricular electrode 12 and the indifferent electrode 16 to sense spontaneous ventricular events in the heart.

In order to detect stimulated ventricular events, the control device 24 operates as follows: After an approved atrial event, spontaneous or evoked, the ventricle is sensed for a spontaneous ventricular event during a time period referred to as the A-V interval. If no spontaneous ventricular event is sensed during the A-V interval, the control device 24 orders the emission of a ventricular stimulation pulse. At the same time the control device's 24 logic is activated to sense whether the ventricular comparator 30 emits a detection signal in the time window for which the logic is activated. If a ventricular event is sensed during the time window, evoked response is established. The control device 24 can then proceed and activate the logic for sensing a spontaneous atrial event. Otherwise, a new ventricular stimulation pulse, containing a higher energy than the last, must be delivered to the ventricle.

Atrial stimulation pulses are emitted when no spontaneous atrial stimulation pulse is sensed within an A-A interval from the last atrial event (spontaneous or stimulated). For the atrium, every stimulation pulse does not have to be checked for evoked response. Checking only e.g. every third atrial stimulation pulse is fully sufficient. In order to facilitate detection of the weaker atrial signal, a biphasic

stimulation pulse is delivered to the atrium. As a result, polarization of the electrode 8 does not persist too long. At the same time, the control device's 24 logic is activated in order to identify a detection signal from the atrial comparator 28 as an atrial event. For safety's sake, the further detector 32 is also activated during the same period of time. The further detector 32 ensures that no ventricular extra systoles are spuriously sensed as stimulated atrial events. The further detector 32 transmits detection signals to the control device 24 and receives control signals from same in the same way as the detector 26.

The heart stimulator 2 also comprises a telemetry unit 34 which is connected to the control device 24 and which can telemetrically receive and transmit information to/from an extracorporeal programming unit 36. With the programming unit 36, a physician can e.g. retrieve stored information from the control device 24 and even re-program the heart stimulator's 2 parameters.

FIG. 3 shows an alternative design for the detector 26 for detecting both atrial and ventricular signals. In a signal conditioning unit 38, input signals from the electrode conductors 10, 14 are conditioned in the same way as in FIG. 2. In this instance, however, only one comparator 40 is used to compare the output signal with the reference potentials U_A and U_V. A switch 42, controlled by the control device 24, connects the relevant reference potential at any given moment. In other words, the atrial reference potential U_A is switched to the comparator 40 when atrial events are to be sensed, and the ventricular reference potential U_V is switched to the comparator 40 when ventricular events are to be sensed.

FIG. 4 shows yet another conceivable version of the detector 26. After signal conditioning in a signal conditioning unit 44, the conditioned signal is sent to a variable amplifier 46. The gain of the variable amplifier 46 is controlled by the control device 24. The output signal from the amplifier 46 is then compared in a comparator 48 with a uniform reference potential U_{ref}. Depending on whether atrial or ventricular events are to be sensed, the control device 24 changes the gain of the variable amplifier 46.

Claims

1. Heart stimulator (2) comprising a pulse generator (18) and an electrode system (6) which comprises an atrial electrode (8), arranged in an atrium of a heart (4), and a ventricular electrode (12), arranged in a ventricle of the heart (4), whereby stimulation pulses, generated by the pulse generator (18), are delivered to the atrium via the atrial electrode (8) or to the ventricle via the ventricular electrode (12) for stimulating a heart event, **characterized by** a detector (26) connected to the atrial electrode (8) and the ventricular electrode (12) for sensing stimulated ventricular heart events.

2. Heart stimulator according to claim 1, **characterized by** a control device (24) connected to the detector (26) for activating same for a predetermined time window in conjunction with the pulse generator's (18) emission of ventricular stimulation pulses in order to sense stimulated ventricular heart events.

3. Heart stimulator according to claim 2, **characterized in** that the detector (24) is devised to even sense stimulated atrial heart events, and in that the control device (24) activates the detector (26) in conjunction with every nth atrial stimulation pulse for sensing stimulated atrial events, n being a predetermined whole number, preferably between 1 and 6.

4. Heart stimulator according to claim 3, **characterized in** that the pulse generator (18) generates a biphasic atrial stimulation pulse or some other polarization-compensating pulse when a stimulated atrial event is to be sensed.

5. Heart stimulator according to claim 3 or 4, **characterized in** that the electrode system (6) comprises an indifferent electrode (16), located outside the heart (4), in that a further detector (32) is connected to the ventricular electrode (12) and the indifferent electrode (16) for sensing spontaneous ventricular events and in that the further detector (32) is activated at the same time as the detector (26) is activated in order to sense stimulated atrial events.

FIG 1

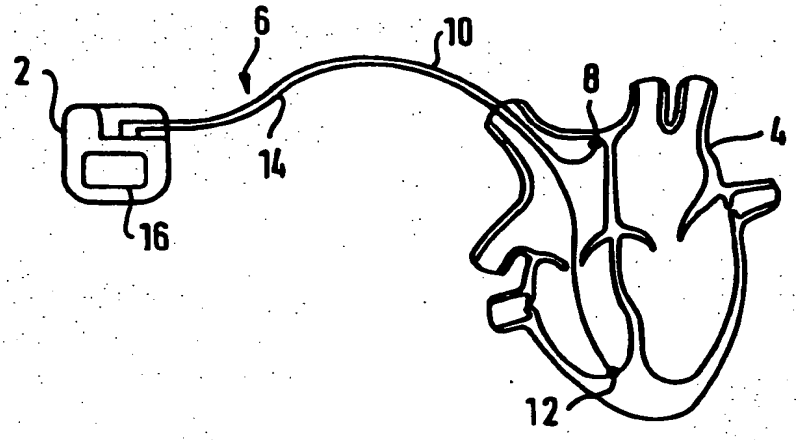


FIG 2

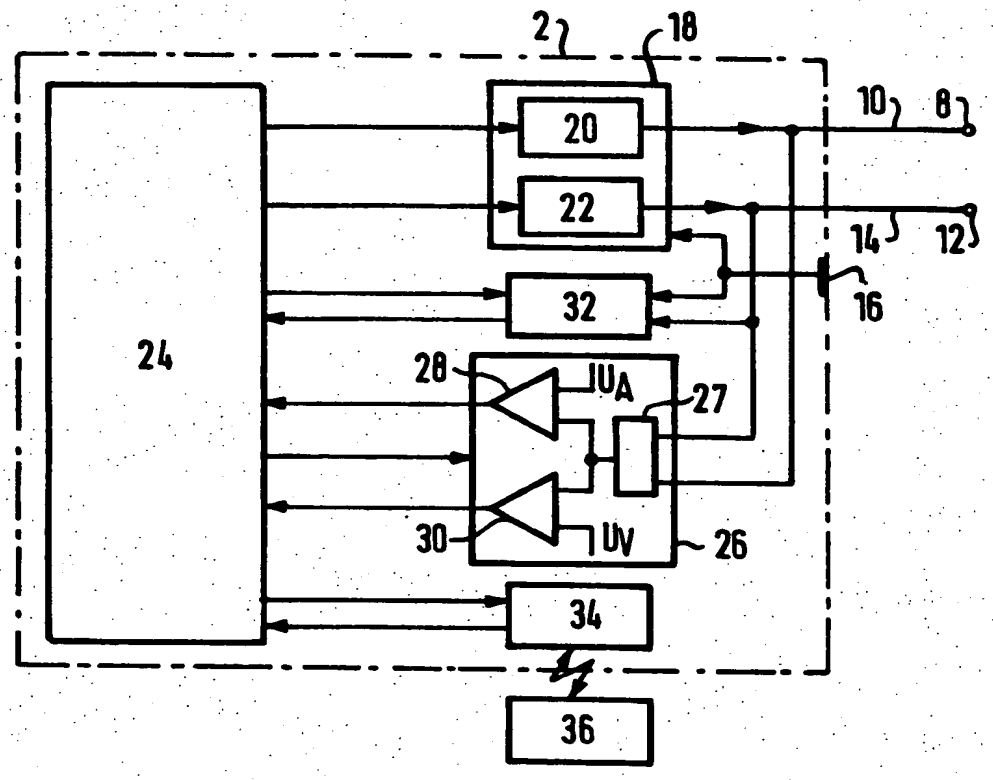


FIG 3

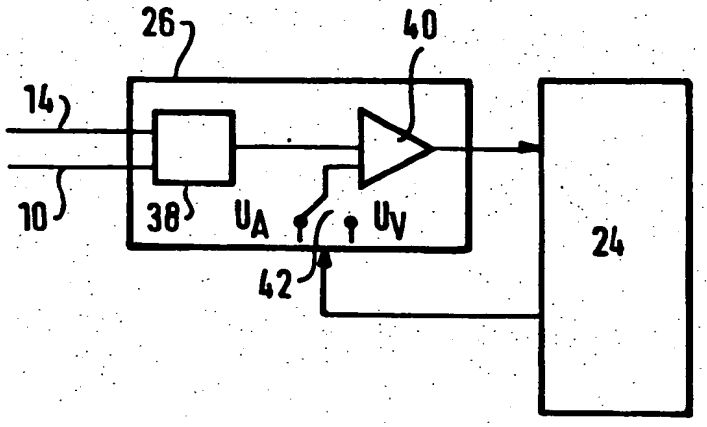
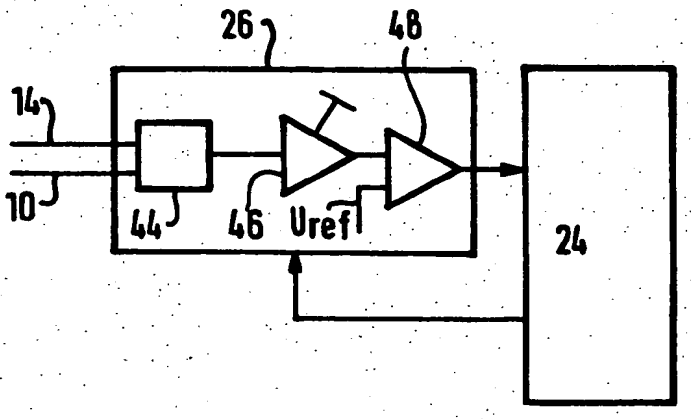


FIG 4



European Patent Office

EUROPEAN SEARCH REPORT

Application Number
EP 94 11 1079.3

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl.5)
X	US, A, 4858610 (CALLAGHAN ET AL.), 22 August 1989 (22.08.89) * column 2, line 17 - line 22; column 3, line 22 - line 28; column 3, line 32 - line 36, figures 5,11 *	1-2	A61N 1/368
Y	--	3-4	
Y	US, A, 4729376 (DECOTE, JR.), 8 March 1988 (08.03.88) * abstract *	3-4	
A	--		
	EP, A1, 0308536 (SIEMENS-ELEMA AB), 29 March 1989 (29.03.89)	1-5	

			TECHNICAL FIELDS SEARCHED (Int. Cl.5)
			A61N

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
STOCKHOLM	25 October 1994	LINDBERG PER

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
Y : particularly relevant if combined with another document of the same category
A : technological background
O : non-written disclosure
P : intermidiate document

T : theory or principle underlying the invention
E : earlier patent document, but published on, or after the filing date
D : document cited in the application
L : document cited for other reasons

& : member of the same patent family, corresponding document

EPO FORM 1503 03.82 (P0401)